REMARKS

TERMINAL DISCLAIMER

The Examiner maintains the rejection of claims 27-38 under the judicially created doctrine of obviousness-type double patenting over the corresponding claims of U.S. Patent No. 5,959,050 (hereafter '050) (*see* Office Action, on page 2, in paragraph 2).

Applicants again offer to file a Terminal Disclaimer, so that the term of this patent will not extend further than the term of '050.

REJECTION UNDER 35 U.S.C. §§ 102 & 103

The Examiner maintains the rejection of claims 27-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by, or alternatively under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent 5,110,833 (hereinafter '833; *see* Office Action, on page 2, in paragraph 3).

Applicants respectively traverse the rejection of claims 27-38 under 35 U.S.C. § 102(b). All of the elements of the claimed invention must be disclosed, expressly or inherently, in a single prior art reference for the requirements for anticipation under 35 U.S.C. § 102 to be met. Patent '833 does not disclose all of the claimed elements of Applicants' invention.

Applicants respectfully traverse the alternate rejection of claims 27-58 under 35 U.S.C. §103 (a) as set forth below. The establishment of a *prima facie* case of obviousness requires that the cited document must teach or suggest all elements of Applicants' claimed invention, there must also be a suggestion or motivation to modify or combine references to achieve the claimed invention, and there must be a reasonable expectation of success to practice the claimed invention. Further, the cited documents must not teach away from Applicants' claimed invention.

Patent '833 reference does not explicitly disclose, teach or suggest the use of particles less than 5 microns or the advantages achieved using such particles. Patent '833 also does not provide any specific examples using particles which fall within the claimed range and does not anticipate or suggest the currently claimed range with "sufficient specificity" (*see* MPEP 2131.03) to support the instant rejection.

Furthermore, '833 does not teach or suggest the use of particles having a size less than 5 μm. The biocompatibility of the particles of the instant invention is a characteristic of the inventive particles of this claimed range. "Applicants disclose that preferably, they must be of the size not more than 5 μm or the size of normal biological antibodies, most preferred 10-100 nm" (*see* specification, on page 4, at lines 21-25).

Patent '833 also teaches away from the presently claimed subject matter. Specifically, '833 teaches:

> ... and the resulting bulk polymer was ground and sieved to particles of less than 25 μm.
>
> Chromatography: A 10cm x 4.5mm (i.d.) column was packed as previously described (D.J. O'Shannessy, B. Ekberg and K. Mosbach Anal. Biochem. 177, 144 (1989) and D.J. O'Shannessy, B. Ekberg, L.I. Andersson and K. Mosbach J Chrom. 470, 391 (1989)) ...

(*see* '833, col. 5, lines 38-45)

The cited O'Shannessy reference (hereinafter "O'Shannessy I"; enclosed for the Examiner's convenience), specifically teaches:

> Particles which passed through a 25-μm sieve were extensively defined in acetonitrile and subsequently constituted a fraction of less than 25 μm.

(*see* O'Shannessy I, page 145).

O'Shannessy I teaches a skilled artisan to throw away what Applicants regard as their invention. Term 'define' means to remove fine particles, or particles less than indicated size. Defining is a necessary step in chromatographic column packing in order to remove small particles that could clog a column. O'Shannessy I teaches the removal and the discarding of any fine particles having a size less than 25 μm. Therefore, '833 teaches the removal of the fine particles of the instant invention and teaches away from the present invention.

Similarly, the second O'Shannessy reference (hereinafter O'Shannessy II; enclosed), cited in '833, describes the particles of the present invention as 'dust' and explicitly teaches the removal of such particles which teaches away from the present invention:

> Particles which passed through a 25-μm sieve constituted a fraction of <25 μm. In all cases, dust was removed by flotation in acetonitrile, and the particles were dried under vacuum.

(*see* O'Shannessy II, page 393, emphasis added).

Contrary to the teaching of '833, the claimed invention requires the use of particles having a size less than 5 microns:

> Preferably, they must be of the size not more than 5 μm or the size of normal biological antibodies, most preferred 10-100 nm.

(*see* Specification, on page 4, at lines 21-25).

> The fines, that is particles with the size of 10-100 or 1000 nm, resulting from grinding, can be kept in solution or suspension and used for instance in so-called homogeneous immunoassays.

(*see* Specification, on page 4, at lines 29-32).

Accordingly, '833 does not disclose or suggest the claimed invention and, in fact, teaches away from the present invention.

Therefore, the rejection of claims 27-38 under 35 U.S.C. 102(b) or, in the alternative, under 35 U.S.C. 103(a) is not proper and Applicants respectfully request the withdrawal of these rejections.

NEW CLAIMS

Applicants herein add new claim 39 which recites "biocompatible" which recitation finds support, e.g., on page 4 of the specification, at lines 21-25. Applicants respectfully traverse the rejection of claims 27-38 under 35 U.S.C. § 102(b).

Applicants note that '833 does not expressly disclose the term "biocompatible". Further, '833 does not disclose:

> If the artificial antibodies are to be used for administration to a mammal body, the polymers must be biocompatible. Preferably they must be of the size not more than 5 μm or the size of normal biological antibodies, most preferred 10-100mm.

(*see* Specification, on page 4, at lines 21-25)

Patent '833 does not appear to disclose either the preferred characteristic of "biocompatible" or the preferred range for particle size for "biocompatible" artificial antibodies.

Applicants not only disclose the "biocompatible" element, but also identify the preferred range: "Preferably, they must be of the size not more than 5 μm or the size of normal biological antibodies, most preferred 10-100 nm" (*see* specification, on page 4, at lines 21-25).

Claim 39 is distinguished over the disclosure of '833. Each of claims 40-45 is dependent either directly or indirectly upon claim 39 and is also distinguished over the disclosure of '833.

CONCLUSION

In view of the above, Applicants respectfully request that the rejection of claims 27-38 under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) be withdrawn. Applicants

assert that the above-identified application is in condition for allowance and request such action at this time.

AUTHORIZATIONS

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deport Account No. 13-4503, Order No. 2324-7028US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN

Dated: December 12, 2002 By: _____

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ATTACHMENT 1

In this attachment, all additions are shown underlined (e.g., the) and deletions are shown by strikethrough (e.g., ~~the~~).

IN THE CLAIMS

Please enter new claims 39-45.